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BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			EXAMINER DEJONG, ERIC S	
			ART UNIT 1631	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/073,463	<b>Applicant(s)</b> RZHETSKY ET AL.	
	<b>Examiner</b> ERIC S. DEJONG	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/13/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED OFFICE ACTION**

Applicants response filed 06/13/2008 is acknowledged. It is further acknowledged that applicants petition for revival after abandonment under 37 CFR 1.137(b), filed 06/13/2008 has been granted (see Petition decision mailed 07/25/2008).

Claims 1- 35 are canceled. Claims 36-45 are currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 06/13/2008 is acknowledged. The WO 99/66067 (Stoughton et al.) has not been considered as no copy of the foreign document has been provided by applicants. The remaining reference in said information disclosure statement has been considered by the examiner.

***Specification***

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of applicants amendment to the instant specification, filed 06/13/2008.

***Claim Objections***

The objection to claim 38 because of minor informalities is withdrawn in view of amendments made to the instant claim, filed 06/13/2008.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 37, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36, 37, and 39-42 each recite the use of a plurality of equations for determining probability and molecular interaction. It is further acknowledged that the instant specification does disclose said equations labeled 5, 6, 10, 14, and 17 and definitions for the terms recited therein. However, the equations recited in the instant claims fail to define the terms used therein and, therefore, cause the metes and bounds of the instant claims to be unclear. It is further noted that, MPEP 2173.05(s) states that where possible, claims are to be complete in themselves and incorporation by reference

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to the specification to specific figures or tables is permitted only in exceptional cases and where it is more concise to incorporate by reference the duplicate drawing or table in the claim. Further, applicants have not presented any arguments or rational as to why defining said terms in the instant claims would present an exceptional case that justifies the incorporation by reference of said equations into the instant claims.

For the benefit of applicants, this rejection could be overcome by an amendment to the instant claims to recite the definitions of the terms used the above described equations.

### ***Response to Arguments***

Applicant's arguments filed 06/13/2008 have been fully considered but they are not persuasive.

In regard to the rejection of claims under 35 USC 112, 2nd paragraph, applicants argue that applicants have been amended to recite the equations themselves rather than an equation number.

In response, it is acknowledged that the instant claims have been amended to recite specific equations and no longer improperly incorporates said equations by reference to the instant specification. However, applicants amendment fails to provide any definition of the terms used in said equations (see also pages 3 and 4 of the previous Office action, mailed 11/20/2007). Therefore applicants argument is not persuasive as applicants amendments to the instant claims have not addressed this issue.

***Claim Rejections - 35 USC § 101***

The previous rejection of claims 36-45 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the holding set forth in the recent CAFC decision regarding *Bilski v. Warsaw* (2008). The grounds of the following rejection are newly applied and therefore constitutes a new grounds of rejection not necessitated by applicants amendments to the instant claims.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36-45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. In the instant case, the claims are drawn to methods for identifying and using a molecular interaction network representation for a set of interacting molecules. The recited processes only involve abstract and computational processing steps that are neither tied to a particular machine nor transforms a particular article into a different state or thing. As such, the instant claims fail the patent eligibility test as set forth in the en banc *Bilski* decision and wholly preempt an abstract, computational series of mental steps and, therefore, are not statutory subject matter.

***Response to Arguments***

Applicant's arguments filed 06/13/2008 have been fully considered but are moot in light of the new grounds of rejection set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Eisenberg et al. (US Patent No. 6,772,069).

The instant claims are drawn to a method for identifying a molecular interaction of a molecule within a biological network of interacting molecules comprising the steps of identifying a conserved feature of said molecule, determining probabilities of attraction between the conserved features and other interacting molecules based on known molecular interaction data, determining probabilities of molecular interaction of said molecules with each other interacting molecules based on the attraction probabilities, identifying the molecular interaction of said molecule corresponding to the determined probabilities of molecular interactions and providing the identification of the

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molecular interaction corresponding to the highest determined molecular interaction probabilities to a user or further processor.

Eisenberg et al. sets forth a computational method, system and computer program for inferring functional links from conserved genomic sequences (see Eisenberg et al., Abstract). Eisenberg et al. teaches the comparison of conserved genomic sequences to identify single protein chain sequences (Rosetta Stone sequences) that are further relied upon to determine interactions between protein components (see Eisenberg et al., Figure 11 and col. 3, lines 1-17 and lines 36-47), which reads on identifying a conserved feature of a molecule within a biological network, as recited in claim 38, and conserved features of a protein domain, as recited in claim 43. Eisenberg et al. further discloses the determination of the distance between two proteins by comparing the phylogenetic profiles of different proteins. This process includes constructing a conditional probability matrix,  $p(aa \rightarrow aa')$ , for proteins within a family that are grouped together on the basis of sequence homology (see Eisenberg et al. col. 4, lines 18-67), which reads on the determination of probabilities of attraction between conserved features of said molecule and other interacting molecules based on molecular interaction data as recited in claim 38. Eisenberg et al. further discloses accounting for conserved alignment in the constructed conditional probability matrix by taking the product of the conditional probabilities for each aligned pair of sequence using the equation  $P(p) = \prod p(aa_n \rightarrow aa'_n)$  (see Eisenberg et al., col.4, lines 42-67), which reads on determining the probability of molecular interaction based on the probabilities of attraction as recited in claim 38. Eisenberg et al. further discloses the



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subsequent determination of a distance  $a$  from powers equation  $p'=p^a (aa \rightarrow aa')$  and maximizing for  $P$  in the above equation for  $P(p)$ , which reads on the identification of said molecule corresponding to the highest determined probabilities of molecular interactions as recited in claim 38. Eisenberg et al. further discloses exemplary results from applications of the above described method (see Eisenberg et al., Table III and col. 26, line 13 through col. 29, line 6), which reads on providing the identification of a molecular interaction corresponding to the highest determined molecular interaction probability to a user as recited in claim 38.

### ***Response to Arguments***

Applicant's arguments filed 06/13/2008 have been fully considered but they are not persuasive.

In regard to the rejection of claims 38 and 43 under 35 U.S.C. 102(e) as being anticipated by Eisenberg et al., applicants argue that Eisenberg does not teach “determining probability of attraction between conserved features” as recited in the instant claims.

In response, it is noted reiterated from the instant rejection that Eisenberg et al. discloses the determination of the distance between two proteins by comparing the phylogenetic profiles of different proteins. This process includes constructing a conditional probability matrix,  $p(aa \rightarrow aa')$ , for proteins within a family that are grouped together on the basis of sequence homology (see Eisenberg et al. col. 4, lines 18-67), which reads on the determination of probabilities of attraction between conserved

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features of said molecule and other interacting molecules based on molecular interaction data as recited in claim 38. In the instant case, neither the instant claims nor specification provides an explicit definition wherein the determining probability of attraction between conserved features excludes embodiments such as the grouping together of proteins within a family on the basis of sequence homology. Rather, the scope of the recited term “probability of attraction between conserved features” is significantly broad and encompasses any and all potential attractions between any conserved features. Therefore applicants argument is not persuasive.

Applicants further argue Eisenberg et al. does not teach determining probabilities of molecular interactions of said molecules with each of the other interacting molecules based on probabilities of interaction and, further, the determination of evolutionary distance as described by Eisenberg et al. does not disclose or suggest determining molecular interactions in any way.

In response, it is noted that applicants argument amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The limitation argued by applicants is extremely broad in scope in that it requires a determination of molecular interaction probability for any and all types of interaction. Further, the recitation of “based on the probability of attraction” is met by any use or reliance on an “attraction probability”. Applicants arguments fail to point out how the generic language

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of the instant claims expressly excludes the specific embodiments as set forth in Eisenberg et al. Therefore, applicants argument is not persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisenberg et al. (US Patent No. 6,772,069) as applied to claims 38 and 43 above, and further in view of Askenazi et al. (US Patent No. 6,594,587, see the references cited by the examiner mailed 11/15/2004) and in view of Friend et al. (US Patent No 6,203,987), as evidenced by Perlin (US Patent No. 5,604,100).

The instant claims are drawn to related methods for identifying a molecular interaction of a molecule within a biological network of interacting molecules comprising determining attraction probabilities between pairs of molecules based on known molecular interaction data, determining an edge probability  $P(E)$ , which is the probability of a single network having a particular edge set, for each possible network interaction of a set of interacting molecules, determining a network topology  $P(\text{topology})$ , which is the probability that a network has a particular distributions of edges for a given vertex, based on the possible molecular interactions for a given network, determining a network probability for each molecular interaction as a product of said edge probability and topology probability, determining a posterior probability of for each molecular interaction network, and identifying the possible molecular interaction having the highest posterior probability. Further recited embodiments include the use of equation 10 for determining posterior probability, the use of equations 6 and 14 for determining attraction probabilities, the use of equations 5 and 17 for determining molecular probability of interaction, and further introducing a compound into a biological network and determining if the compound is being capable of modifying the interaction between molecules in a given network.

As discussed above, Eisenberg et al. sets forth a computational method, system and computer program for identifying functional links and conserved genomic sequences to identify conserved protein sequences and interactions between protein components (see Eisenberg et al., Abstract and col. 3, lines 1-17 and lines 36-47). However, Eisenberg et al. does not teach the determination of an edge probability, a

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network topology probability, a network probability, a posterior probability, or the use of equations 5, 6, 10, 14, and 17 as recited in claims 36, 37, and 39-42. Further, Eisenberg et al. does not teach the use of the disclosed method for testing whether a compound is capable of modifying the interaction between at least two molecules in a biology network as recited in claims 44 and 45.

Askenazi sets forth a robust method for determining associations among a set of biological elements using algorithms for generating a Steiner tree, which is a network representation of associated biological elements (see Askenazi, Abstract, Figure 1, and col. 6, line 5 through col. 7, line 15). The disclosed method comprises computationally deriving relationships among a set of biological elements, wherein the biological elements are represented as vertices and the interactive relationships between said biological elements are represented as edges (see Askenazi, col. 2, lines 30-52).

Askenazi further discloses embodiments wherein vertices represent enzymes (proteins) and substrates and wherein edges represent enzyme-enzyme and substrate-enzyme interactions (see col. 5, lines 42-61). The representation of associations between biological elements is taught as a heuristic modeling approach that results in the determination of the most efficient connection between vertices and edges of the graph corresponding to a "Context Set" (see especially Askenazi, col. 6, line 57 through col. 7, line 3). Askenazi further teaches that the output of the disclosed method is a "Steiner subgraph", which is a combination of a plurality of Steiner Trees solutions all having the same number of edges and vertices and edges (see Askenazi, col. 7, lines 4-15).

While Eisenberg et al. teaches the above described method for identifying functional links between conserved protein sequences and identifying interactions between protein components and Askenazi teaches a method for determining associations among a set of biological elements, neither Eisenberg et al. nor Askenazi teach the use of equations 5, 6, 10, 14, and 17 as recited in claims 36, 37, 39-42. Further, neither Eisenberg et al. nor Askenazi teach the use of the disclosed method for testing whether a compound is capable of modifying the interaction between at least two molecules in a biology network as recited in claims 44 and 45.

Friend et al. sets forth methods for enhanced detection of biological response patterns, classifying cellular constituents, such as measurable protein activities, into groups based upon the covariation among said constituents, and drug discovery (see Friend et al., Abstract and col. 2, lines 21-41). Friend et al. discloses embodiments of the method wherein statistical algorithms are relied to derive a "clustering tree" to model resultant patterns between related cellular constituents in response to cellular perturbations (see Friend et al., col. 1, lines 51-62 and col. 2, line 42 through col. 3, line 12). Friend et al. further specifies embodiments that rely upon objective statistical tests to define truly distinct branches within a clustering tree derived from a Monte Carlo modeling approach. While Friend et al. does not expressly teach the use of equations 5, 6, 10, 14, and 17 to determine posterior probability, attraction probabilities, molecular probability of interaction, said equations are taught by the instant specification as being derived from known statistical Monte Carlo sampling methods (see paragraph 0006 of the instant specification). Perlin is relied upon in the instant rejection as providing

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evidence that Markov chain Monte Carlo statistical techniques in Bayesian network approaches are well known in the art as being applied to the modeling biological systems (see Perlin, col. 16, lines 52-63). One of ordinary skill in the art would recognize that known applications of Markov chain Monte Carlo statistical techniques would have yielded predictable results and, further, would have resulted in the derivation and use of equations 5, 6, 10, 14, and 17 as instantly claimed. Friend et al. further discloses illustrative drug discovery applications wherein a drug candidate (test compound) is introduced into a model of cellular constituents (see Friend et al., col. 17, line 8 through col. 18, line 44). Following the introduction of a drug, the resultant perturbations to the model of cellular constituents is relied upon to evaluate (screen) the potential efficacy of said drug.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to combine the method for identifying functional links and interactions between conserved protein sequences, as taught by Eisenberg et al., the method for determining associations among a set of biological elements wherein said biological elements are represented as vertices and interactive relationships between said biological elements are represented as edges, as taught by Askenazi, and the method for enhanced detection of biological response patterns and classifying cellular constituents into groups based upon the covariation among said constituents, as taught by Friend et al., to arrive at the instantly recited methods for identifying a molecular interaction network representation. One of ordinary skill in the art could have combined the known methods disclosed in the prior

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art to yield a predictable result because each of said methods performs the same function either separately or in combination.

### ***Response to Arguments***

Applicant's arguments filed 06/13/2008 have been fully considered but they are not persuasive.

In regards to the rejection of claims 36-45 under 35 USC 103(a) as being unpatentable over Eisenberg et al. in view of Askenazi et al. in view of Friend et al. , as evidenced by Perlin, applicants set for the basis for establishing a *prima facie* case of obviousness. Applicants further argue that there is no motivation to combine references applied in the instant rejection, that the cited references are concerned with solving different problems, and there is no reason or likelihood of success.

In response, applicants characterization of the legal basis for a *prima facie* case of obviousness is not agreed with by the examiner as it is contradictory to the holdings set forth by the Supreme Court in the recent decision in KSR v. Teleflex (2007). The recent Supreme Court decision in KSR Intl. Co. v. Teleflex Inc. rejected the rigid approach of applying a strict TSM test as the sole basis for obviousness and that the analysis for obviousness need not seek out precise teachings directed to the specific subject matter of a claim. Further the decision set forth that the analysis can take into account the inferences and creative steps that a person of ordinary skill in the art could employ and that a person of ordinary skill in the art is also a person of ordinary creativity, not an automaton. Further, the decision set forth that a combination of familiar



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elements according to known methods is likely to be obvious when it does no more than yield predictable results. Therefore applicants argument is not persuasive.

Applicants further argue that organizing data as a Steiner tree, as set forth by Askenazai et al., does not disclose or suggest an edge probability or determining any probabilities at all.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants argument does considers the disclosure of Askenazai et al. in isolation from the teachings of Eisenberg et al., Friend et al., and Perlin when the instant rejection is relies on the combination of teachings from all of the applied references from the perspective of one having ordinary skill in the art. As such, applicants arguments directed to the insufficiencies of the teachings of Askenazai et al. are not persuasive.

Applicants further state that determining a posterior probability of said each molecular interaction network using [equation 10]" is not obvious in view of Friend et al. and Perlin.

In response, applicants statement alone is not sufficient to differentiate the instant claims from that which is set forth in the prior art. Such an "argument" amounts

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to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S DeJong/  
Primary Examiner, Art Unit 1631

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